

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555-0001

March 15, 2007

NRC INFORMATION NOTICE 2007-10: YTTRIUM-90 THERASPHERES® AND
SIRSPHERES® IMPURITIES

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this Information Notice (IN) to alert addressees to the presence of radioactive contaminants in two variations of commercially available Yttrium-90 (Y-90) labeled microspheres, "SIRspheres®" and "TheraSpheres®," manufactured by Sirtex Medical, Inc. and MDS Nordion, respectively and the possible problems with their disposal in accordance with 10 CFR 35.92. Recipients should review the information, contained in this IN, for applicability to their facilities, and consider actions, as appropriate. However, recommendations contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

NRC is providing this IN to the Agreement States for their information, and for distribution to their medical use licensees, as appropriate.

BACKGROUND

TheraSpheres® and SIRspheres® are therapeutic devices that deliver radiation directly to tumors in the liver, using glass or resin microspheres. Y-90 is either integrated into the glass matrix or attached to the resin beads with diameters from 15 to 35 microns (μ). Millions of these microspheres are injected into the hepatic artery, the liver's main blood vessel, in a manner that preferentially traps them in the capillary bed feeding the tumor, and not the larger blood vessels feeding healthy tissues. The SIRspheres® and TheraSpheres® are designed to deliver radiation directly to tumors, while sparing healthy tissues.

DESCRIPTION OF CIRCUMSTANCES

On March 20, 2006, the staff at the Vanderbilt University, Department of Radiology and Radiological Science, informed NRC's Operation Center of its discovery of the presence of radioactive contaminants in SIRspheres® and TheraSpheres®. As a follow-up, on March 21, 2006, Vanderbilt University staff, in a letter to the Radiological Devices Branch of the U.S. Food and Drug Administration (FDA), explained that they detected contaminants in the samples by using a high-purity germanium detector.

ML063470020

The Y-90 SIRSpheres® sample contained detectable amounts of Yttrium-88 (Y-88), with a half-life of 106.6 days and the TheraSpheres® sample had measurable amounts of the following radionuclides: Y-88; Europium-154 (half-life 8.8 years); Europium-152 (half-life 13.6 years); Cobalt-57 (half-life 270.9 days); and Cobalt-60 (half-life 5.27 years). It is important to note that only one sample from each device was analyzed. Further characterization of radioactive levels in more samples may yield more accurate results.

DISCUSSION

The main reason the Vanderbilt University, Department of Radiology and Radiological Science reported this issue, to both NRC and FDA, was because the samples of TheraSpheres®, held for decay-in-storage, appeared to be radioactive for much longer than would have been expected, because of the presence of Y-88 and other contaminants.

The staff at the Vanderbilt University, Department of Radiology and Radiological Science performed a preliminary evaluation of the radiation dose that might be delivered to the liver of an adult, assuming 100 percent of the activity of the microspheres containing contaminants was distributed uniformly in the liver and was removed only by physical decay. Based on this evaluation, the dose to the liver from the contaminants did not exceed the medical event limit, i.e., the dose delivered did not differ from the prescribed dose by 20 percent or more, and did not differ from the prescribed dose by more than 0.5 Sv (50 rem) to an organ. However, licensees should be concerned with disposal of microspheres. Depending on the contaminants, licensees may need to: (1) hold the remaining microspheres longer in decay-in-storage, in accordance with 10 FR 35.92; (2) return the microspheres to the manufacturer; or (3) transfer to an authorized recipient according to 10 CFR 20.2006.

CONTACTS

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact below.

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Janet R. Schlueter, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Mohammad S. Saba, FSME
Phone: 301-415-7608
E-mail: mss@nrc.gov

Enclosure: List of Recently Issued NMSS/FSME
Generic Communications

Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
12/13/06	RIS-06-27	Availability of NRC 313A Series of Forms and Guidance for their Completion	All NRC medical-use licensees, commercial nuclear pharmacies, and U.S. Nuclear Regulatory Commission (NRC) Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
12/7/06	RIS-06-26	TRAINING AND EXPERIENCE AND GRANDFATHER PROVISIONS FOR AUTHORIZED MEDICAL PHYSICISTS UNDER 10 CFR PART 35	All NRC medical licensees and Radiation Control Program Directors.
12/7/06	RIS-06-25	Requirements For The Distribution And Possession Of Tritium Exit Signs And The Requirements In 10 CFR 31.5 AND 32.51a	All U.S. Nuclear Regulatory Commission (NRC) licensees distributing tritium exit signs and those possessing a tritium exit sign under a general license.
11/15/06	RIS-06-22	Lessons Learned From Recent 10 CFR PART 72 Dry Cask Storage Campaign	All Title 10 <i>Code of Federal Regulations</i> (10 CFR) Part 72 specific licensees and certificate holders and holders of operating licenses for nuclear power reactors (including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel) that are not 10 CFR Part 72 specific licensees.
09/22/06	RIS-06-14	Enforcement Discretion for Facility Changes Under 10 CFR 70.72(c)(2)	All fuel cycle licensees regulated under Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 70, Subpart H.
09/14/06	RIS-06-20	Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems	All community water systems (CWSs), in U.S. Nuclear Regulatory Commission (NRC) non-Agreement States, that during the treatment of drinking water, may accumulate and concentrate naturally-occurring uranium in media, effluents, and other residuals, above 0.05 percent by weight.
09/14/06	RIS-06-19	Availability of Guidance on Radioactive Seed Localization	All NRC medical licensees.
08/31/06	RIS-06-18	Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients	All NRC medical licensees.

Date	GC No.	Subject	Addressees
08/15/06	RIS-06-16	Transfer of the Management Oversight Of Certain NRC Region I Licensees in Mississippi To the NRC Region IV Office	All NRC materials licensees.
07/20/06	RIS-06-11	Requesting Quality Assurance Program Approval Renewals Online by Electronic Information Exchange	All 10 CFR Part 71 quality assurance program and certificate holders.
04/23/06	RIS-06-10	Use of Concentration Control for Criticality Safety	All licensees authorized to possess a critical mass of special nuclear material.
01/26/06	RIS-02-15, Rev. 1	NRC Approval of Commercial Data Encryption Products For the Electronic Transmission Of Safeguards Information	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
01/24/06	RIS-06-01	Expiration Date for NRC-Approved Spent Fuel Transportation Routes	The U.S. Nuclear Regulatory Commission (NRC) licensees who transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel (SNF)).
01/13/06	RIS-05-27, Rev. 1	NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review	All 10 CFR Parts 71 and 72 licensees and certificate holders.
11/14/06	IN-06-25	Lessons Learned From NRC Inspection Of Control And Accounting Of Special Nuclear Material At Commercial Nuclear Power Reactors	All power reactors, category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants. Note that the information notice contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390
11/7/06	IN-06-23	Events Involving Potential Tampering Or Malfeasance By Persons Granted Unescorted Access	All power reactors, category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants. Note that the information notice contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390

Date	GC No.	Subject	Addressees
07/10/06	IN-06-13	Ground-Water Contamination Due to Undetected Leakage of Radioactive Water	All holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor and those authorized by Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 72 licenses to store spent fuel in water-filled structures.
07/06/06	IN-06-12	Exercising Due Diligence When Transferring Radioactive Materials	All materials licensees.
06/12/06	IN-06-11	Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures	All medical licensees.
03/31/06	IN-06-07	Inappropriate Use of a Single-parameter Limit as a Nuclear Criticality Safety Limit	All licensees authorized to possess a critical mass of special nuclear material.
03/21/06	IN-02-23, Supl. 1	Unauthorized Administration of Byproduct Material for Medical Use	All medical licensees.
01/19/06	IN-06-02	Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless- Steel-jacketed Electrical Cables	All holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

Note: NRC generic communications may be found on the NRC public website at <http://www.nrc.gov>, under Electronic Reading Room/Document Collections.